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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/825,359
Applicant	:	GIBSON, PETER
Filed	:	APRIL 16, 2004
Title	:	IMPLANTABLE DEVICE HAVING OSSEOINTEGRATING PROTUBERANCES
Art Unit	:	3762
Examiner	:	TO BE ASSIGNED
Atty Docket No.	:	COCH-0009-1

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The below-identified communication(s) is (are) submitted in the above-captioned application or proceeding:

☒ Certified copy of Australian Provisional Application No. 2003901867

☒ The Commissioner is hereby authorized to charge payment of any fees associated with this communication, including fees under 37 C.F.R. §§ 1.16 and 1.17 or credit any overpayment to **Deposit Account Number 10-0233-COCH-0009-1.**

Respectfully submitted,

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August 16, 2004

Australian Government

Patent Office
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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003901867 for a patent by COCHLEAR LIMITED as filed on 17 April 2003.

CERTIFIED COPY OF
PRIORITY DOCUMENT

WITNESS my hand this
Fourth day of May 2004

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COMMONWEALTH OF AUSTRALIA
AUSTRALIA
PATENT OFFICE

AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Osseointegration fixation system for an implant

The invention is described in the following statement:

Field of the Invention

The present invention resides in a new technique for securely fixing a tissue-stimulating prosthesis, such as a cochlear implant package, in a desired location within a recipient of the prosthesis.

Background of the Invention

Delivery of electrical stimulation to appropriate locations within the body can be used for a variety of purposes. For example, functional electrical stimulation (FES) systems can be used to deliver electrical pulses to certain muscles of a recipient so leading to a controlled movement of the limb of such a recipient.

Electrical stimulation of the cochlea using cochlear implant systems can also be used to directly deliver electrical stimulation to the auditory nerve fibres of a recipient, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

Cochlear implant systems have typically consisted of two main components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to a recipient.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter antenna.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the recipient. This transcutaneous transmission occurs via the external transmitter antenna which is positioned to communicate with an implanted receiver antenna provided with the receiver/stimulator unit.

This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit traditionally includes a receiver antenna that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlear electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The receiver/stimulator unit manufactured by the present Applicant has a package made from titanium which houses the stimulation electronics and which is fitted into a bed created in the mastoid bone. A receiver coil extends from the rear end of the package and lies superficial to the bone. Other cochlear implants have included packages made from a ceramic material which are usually placed completely within the bed drilled down to the dura mater.

Various techniques have been implemented in order to fix the device in place and to ensure that the device does not undergo movement once implanted.

In one method, the housing for a receiver/stimulator unit has been positioned within the head of the recipient by drilling a bed or well into and through the posterior section of the mastoid bone lying behind the recipient's ear. Such a bed is usually made by drilling the bone down to the lining of the brain or dura mater, so that the receiver/stimulator unit is maintained in position and does not protrude excessively past the skull surface. The tight dimensions dimensions of the bed or well relative to the size of the housing together with the eventual growth of a fibrous capsule serves to help retain the housing in its desired position. One disadvantage of this technique is the time taken in the implant surgery to create the bed. A further disadvantage is that there is some potential for the housing to shift out of the well due to an impact to the head of the recipient. Still further, this technique is not always possible depending upon the thickness of the surrounding bone and the age and anatomy of the recipient.

One further technique has involved the positioning of at least one suture or Dacron tie (bioresorbable or non-bioresorbable) across the housing to hold it in place. One problem with this approach is that drilling of the holes into the surrounding bone can be a difficult and time consuming procedure, and especially for young children, much care must be taken by the surgeon to ensure that the drilling does not perforate the dura mater, as the skull thickness in such cases can be quite thin. Further to this, the suture or Dacron ties may not be sufficiently strong enough to withstand a substantial impact to a region of the head adjacent the device and as a result, such a force may dislodge the device from its desired position. In addition, it has been found that if a suture or Dacron tie is inadvertently placed across an inappropriate section of the device, such as across a strain relief of the electrode lead, the suture/tie may cause the lead/device to undergo fatigue and cause failure at this location.

Therefore, there is a need to provide a fixation method for an implantable hearing prosthesis that is capable of securely maintaining the device in place in a desired region of the recipient's head without the need for additional sutures or ties.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an implantable component of a tissue-stimulating prosthesis for implantation at or adjacent a bony surface of a recipient, the component having a housing and at least one connection member extending outwardly therefrom, the component being characterised in that the connection member is adapted to undergo osseointegration with the bony surface.

Osseointegration is a term coined to describe the formation of a structural connection between living bone and the surface of an implant. It is thought to occur at a molecular level where the implant becomes part of the bone to which the implant has been mounted.

In a preferred embodiment, the tissue-stimulating prosthesis is a cochlear implant. The implantable component of the cochlear implant preferably comprises a receiver/stimulator package of such an implant. While the present application will hereinafter refer to cochlear implants, it is to be understood that the invention has a potential wider application to other implantable tissue-stimulating prostheses.

In one embodiment, the housing of the implantable component can be adapted to be placed on the surface of the bone of the recipient, such as the skull. The component is preferably placed on the bony surface under a relatively tight periosteal pocket. In the case of a cochlear implant, this bone would likely be the mastoid process. In another less preferred embodiment, a bed or well can be formed in the surface of the bone, such as the mastoid process, such that the housing can be positioned in the well or bed.

In one embodiment, said at least one connection member can comprise a loop member. Said at least one loop member can extend outwardly and downwardly from the housing. By downwardly, the loop member can be understood to be extending toward the bone of the recipient when the component is mounted on or near the bony surface. Said at least one loop member preferably presses into the bony surface under the pressure applied to the component by the periosteal pocket. Over time, said at least one loop member preferably gradually sinks into and osseointegrates with the bony surface. Once a surface of the housing of the implantable component reaches the level of the bony surface, the implantable component stops gradually sinking into the skull and is so held in place by the loop members that have osseointegrated with the bony surface.

More preferably, the housing has at least two loop members extending outwardly therefrom. In this embodiment, the loop members preferably extend in substantially opposite directions relative to each other.

In one embodiment, the loop members can extend from a surface of the housing that is adapted to be in abutment with, embedded within, or be relatively close to the bony surface.

In a further embodiment, said at least one connection member can comprise a stud member that extends out of a surface of the housing that is adapted to be positioned closest to or in abutment with the bony surface. In one embodiment, the housing can have three stud members extending therefrom. The studs preferably over time osseointegrate with the bony surface and so serve to prevent at least substantial lateral movement of the component. The studs preferably though do not prevent the housing be lifted away from the bony surface in the case where it does become necessary to replace the implantable component or at least the housing.

In yet a further embodiment, said at least one connection member can comprise a fastening member mounted to a support. In one embodiment, the fastening member can comprise a screw, a clip, and/or a nail. In one embodiment, the screw can be countersunk or have a round head. The screw can have a threaded member extending away from the head to a distal end. The head of the screw can have a slot to receive a tool, such as a screwdriver.

In one embodiment, the support can comprise a flange member. In yet a further embodiment, the screw can be threadedly engaged with the wall of an orifice in the flange member. On implantation, the fastening member is preferably not inserted or screwed into the bony surface. Rather, the distal end of each fastening member preferably simply abuts the bony surface under pressure applied by the placement of the housing in a periosteal pocket adjacent the bony surface. Over time, the fastening member osseointegrates with the bony surface.

If it becomes necessary to remove the housing, the fastening members can be removed from the bone and the housing lifted away from the bony surface. Where the fastening member is a screw, the screw preferably is unscrewed from the bony surface using a suitable tool, such as a screwdriver.

In a preferred embodiment, the one or more connection members are adapted to osseointegrate with the bony surface within a period of about 40 days or less.

In one embodiment, the connection member can be formed of titanium. In another embodiment, the connection member can be coated with titanium or have an appropriate surface treatment that encourages osseointegration.

In this and other embodiments, the housing of the implantable component can be formed from a suitable biocompatible material. As it is desirable that osseointegration does not occur between the housing and the bony surface other than via the connection members, it is preferred that the housing be formed from or coated with a material that does not osseointegrate with bone. For example, where the housing is formed of titanium, the housing is preferably coated with another material, such as a suitable biocompatible silicone. In another embodiment, the housing of the implantable component can be formed from suitable biocompatible metallic, ceramic and polymeric materials.

In the case of a cochlear implant, an electrically conducting lead preferably extends from the receiver/stimulator package to an electrode array. The lead preferably exits the package such that it is extendable into the cochlea of the recipient on appropriate positioning of the implantable component within the recipient. In a preferred embodiment, the lead preferably extends from the implanted package to the cochlea via a posterior tympanotomy positioned at the bottom of a mastoid cavity. Other lead positions and geometries are can, however, be envisaged.

The present invention provides a housing of an implantable component having one or more connection members for use in osseointegrating the component to a bony surface of the recipient. In addition to supporting the component, the members have the additional characteristic of serving to protect the component from inadvertent dislodgment following an impact that might otherwise dislodge the component if positioned and mounted using conventional techniques.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a plan view of one embodiment of the present invention;

Fig. 2 is an end view of the embodiment shown in Fig. 1;

Fig. 3 is a side view of the embodiment shown in Fig. 1;

Fig. 4 is a plan view of another embodiment of the present invention;

Fig. 5 is an end view of the embodiment shown in Fig. 4;

Fig. 6 is a side view of the embodiment shown in Fig. 4;

Fig. 7 is a plan view of a still further embodiment of the present invention;

Fig. 8 is an end view of the embodiment shown in Fig. 7; and

Fig. 9 is a side view of the embodiment shown in Fig. 7.

Preferred Mode of Carrying out the Invention

Cochlear implant systems typically rely on use of two main components, namely an external component including a microphone, speech processor, and external antenna, and an implantable component including an antenna, a receiver/stimulator unit, and an electrode array that is positionable within the cochlea. Signals output by the speech processor are transmitted to the receiver/stimulator unit which in turn outputs appropriate signals to the electrode array. These stimulation signals are applied by the array to the basilar membrane and the nerve cells within the cochlea thereby stimulating the auditory nerve.

Various embodiments of the implantable component having the features of the present invention are depicted in the attached figures. In the figures, the electrode array is not depicted for clarity reasons.

One embodiment of the implantable component is depicted generally as 20 in Figs. 1 to 3. In this embodiment, the component 20 has a housing 21 for the electronics of the receiver/stimulator unit, and a silicone-encapsulated receiver antenna coil 22.

The housing 21 is preferably formed from titanium and also encapsulated within a layer of silicone.

Two titanium loop members 23 extend outwardly and downwardly from the housing 21. These loops 23 are sized and shaped to press into the surface of the skull 50 on placement of the component 20 in a periosteal pocket adjacent the skull 50. Over time, such as about 40 days, the loops 23 preferably gradually sink into and osseointegrate with the skull 50. Once the lower surface 24 of the housing 21 reaches the surface of the skull 50, the implantable component 20 stops gradually sinking into the skull 50 and is so held in place by the loops 23 that have osseointegrated with the bony surface of the skull 50.

A further embodiment of an implantable component for placement on the surface of the skull 50 is depicted generally as 30 in Figs. 4-6. In these figures, like features to those depicted in Figs. 1 to 3 are numbered identically.

In this embodiment, a plurality of studs 31 extends out of the lower surface 24 of the housing 21. As depicted, housing 21 can have three studs 31 extending therefrom. The studs 31 preferably over time osseointegrate with the bony surface of the skull 50 and so serve to prevent at least substantial lateral movement of the component 30. The studs 31 preferably though do not prevent the housing be lifted away from the bony surface of the skull 50 in the case where it does become necessary to replace the implantable component 30 or at least the housing 21 thereof.

A still further embodiment of an implantable component is depicted generally as 40 in Figs. 7-9.

In this embodiment, two bone screws 41 are threadedly mounted to respective flanges 42 extending outwardly from the housing 21. Each screw 41 has a slot 43 in the head thereof to receive a tool, such as a screwdriver. On implantation, the screws 41 are preferably not inserted or screwed into the bony surface of the skull 50. Rather, the distal end of each screw is positioned so as to abut the bony surface under pressure applied by the placement of the component 40 in a periosteal pocket adjacent the bony surface. Over time, the screws 41 osseointegrate with the bony surface.

If it becomes necessary to remove the component 40, the screws 41 can be unscrewed from the bone 50 using a screwdriver and the component 40 lifted away from the bony surface.

The flanges 42 can be made from titanium and may be attached to the titanium implant housing 21 by welding. Alternatively, the flanges 42 may be integrally formed with the implant housing 21.

The screws 41 can be surgical screws and preferably have a low profile so they do not cause tissue erosion in the region of their head.

As depicted, the flanges 42 can extend out from the side surfaces of the housing 21 at or adjacent its lower surface 24. It should also be appreciated that other arrangements are possible where the flanges 42 extend from a different location on the housing 21.

It should also be appreciated that the flanges 42 could be made from a plastic or elastomeric materials bonded to the implant housing 21. For example, it may be possible to extend the silicone rubber coating of the implant package 21 to create a silicone rubber flange which may be secured to the skull via the screws 41. Further, it may be possible to embed a plastic material such as PTFE or polyurethane within the silicone rubber coating of the implant housing 21 to form a flange, or even attach such a device to the housing 21 via a mechanical interlock. It may also be possible to make the flange of a composite or combination of materials. For example, a Dacron mesh may be used as a reinforcing structure to strengthen the silicone rubber coating. PTFE, polyurethane or carbon fibre materials may also be used as a reinforcing member.

By providing the flange made from a plastic or elastomeric material it may be possible to allow the surgeon to remove or cut-off the flange during the surgical procedure should they not wish to use such a fixation method, resulting in the fixation mechanism being an optional feature. Such a flange would also be easier to form and alter the shape thereof to more appropriately conform to the shape of the recipient's skull. Further, a flange made from a plastic or elastomeric material is softer than a metallic flange and will therefore be less prone to causing tissue erosion. Still further, the depicted flanges could be removably mounted to the housing so allowing them to be removed if not required.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this seventeenth day of April 2003

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

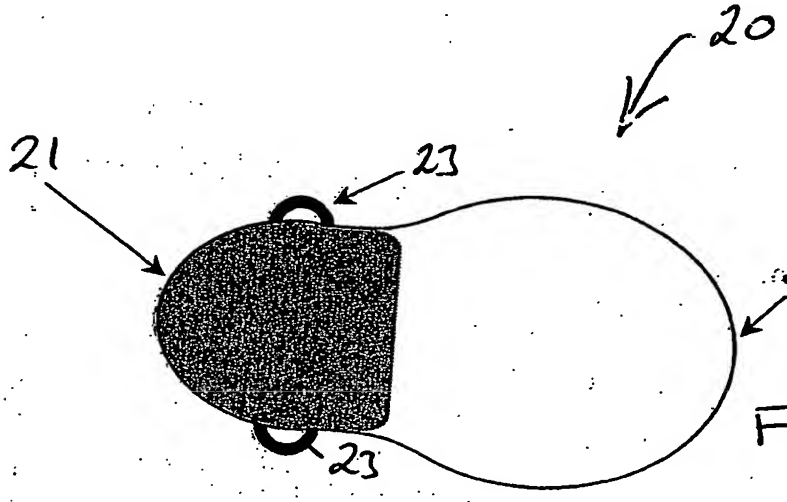

Fig. 1

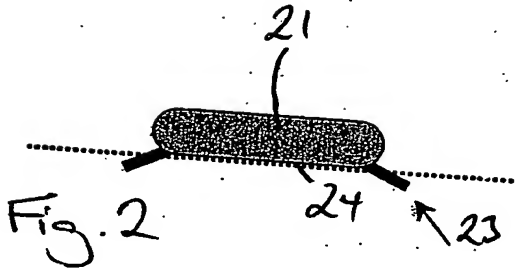

Fig. 2

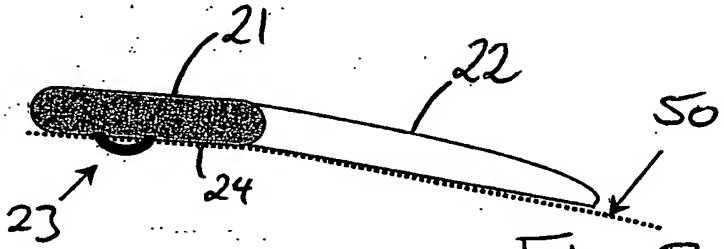

Fig. 3

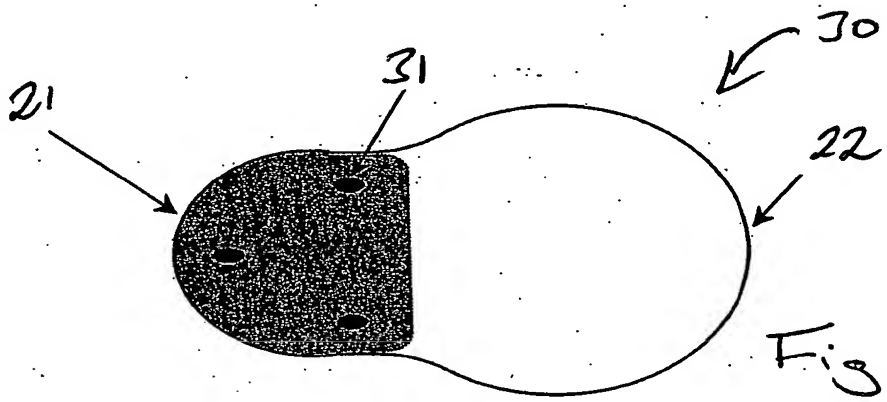

Fig. 4

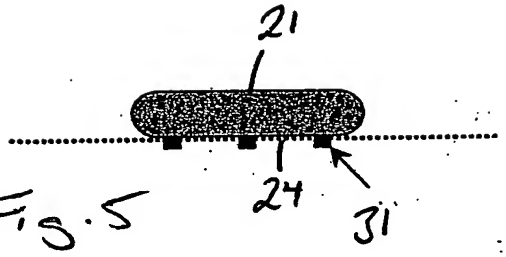

Fig. 5

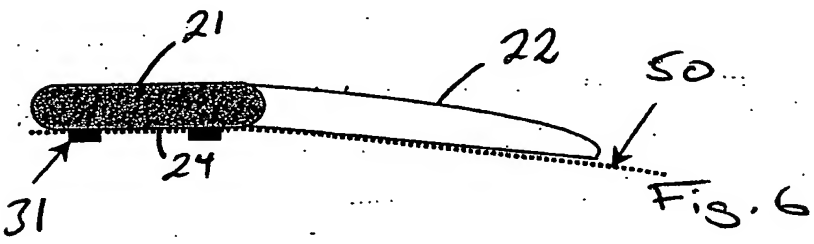

Fig. 6

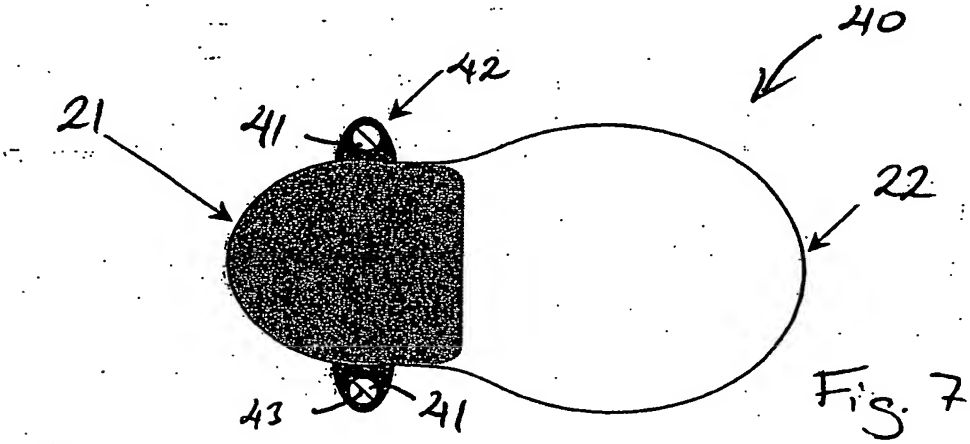

Fig. 7

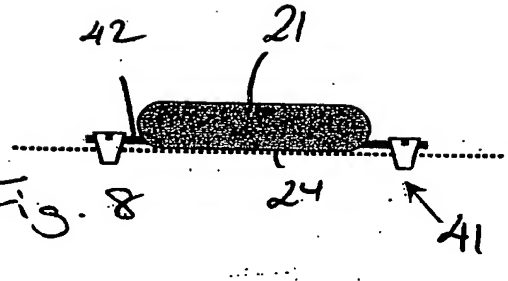

Fig. 8

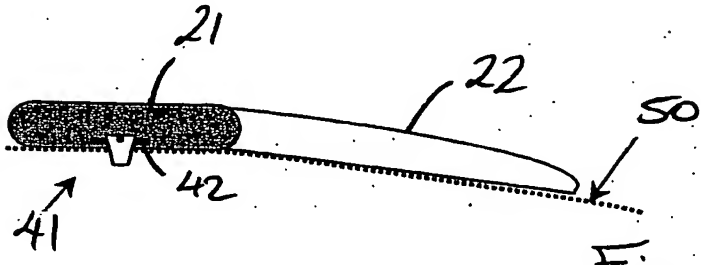

Fig. 9